

PATENT  
144002-2001**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s) : Douglas T. Dieterich  
U.S. Serial No. : 09/862,404  
Filing Date : May 21, 2001  
For : **METHOD OF TREATING ANEMIA CAUSED BY  
RIBAVIRIN TREATMENT OF HEPATITIS C  
USING ERYTHROPOIETIN ALPHA**

Examiner : Regina M. DeBerry  
Group Art Unit : 1647

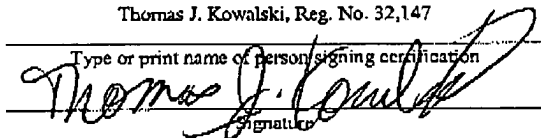
745 Fifth Avenue, New York, NY 10151

**FACSIMILE**

I hereby certify that this paper is being facsimile transmitted to  
the Patent and Trademark Office on the date shown below.

Thomas J. Kowalski, Reg. No. 32,147

Type or print name of person signing certification



December 7, 2004

Date of Signature

**RECEIVED  
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DEC 07 2004****INFORMATION DISCLOSURE STATEMENT**

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

The Examiner's attention is respectfully drawn to the two (2) enclosed documents listed  
on the accompanying PTO Form 1449 and which are listed as follows.

1. "Weisz (1)" Weisz KB, JF Braun, DT Dieterich, PF Hergenroeder, SJ Kreiswirth, MP  
Mullen, AA McMecking, R Tirelli, "Erythropoietin use for ribavirin/interferon-  
induced anemia in Hepatitis C patients," [abstract], Proceedings of the 38<sup>th</sup>  
Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC);  
September 24-27, San Diego, California, 1998

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2. **"Weisz (2)"** Weisz K, T Hau, S Kreiswirth, M McMeeking, J Braun, J Tirelli, AH Talal, DT Dieterich, **"Erythropoietin use for ribavirin/interferon induced anemia in patients with Hepatitis C,"** [poster], Proceedings of the 38<sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC); September 24-27, San Diego, California, 1998.

It is respectfully requested that the Examiner consider and make of record the documents cited herewith and that a copy of Form PTO-1449 be initialed by the Examiner and returned to the undersigned.

The present invention relates to a method for treating hepatitis C in an HIV-negative patient in need thereof comprising administering ribavirin (RBV) or RBV and interferon-alpha (IFN), wherein the improvement comprises administering Erythropoietin (EPO) concomitantly or sequentially or via co-administration with the RBV or with the RBV and IFN and the RBV is administered at a maximum effective dosage wherein said dosage is at or between 800-1200 mg per day. Thus, the invention relates to administering EPO, **either concomitantly or sequentially or via co-administration** with the RBV or the RBV/IFN co-therapy, i.e., during the RBV or RBV/IFN treatment and thus, prior to the onset of RBV-induced anemia.

Applicant respectfully submits that the herewith cited references, Weisz (1) and Weisz (2), do not teach or fairly suggest the present invention as they are both involved in treating anemia, not HCV.

Indeed, it is respectfully submitted that Weisz (1) and Weisz (2) do not relate to the present invention because they do not teach or fairly suggest administering EPO during the HCV RBV or HCV RBV/IFN treatment (concomitant or sequential or co-administration of EPO and RBV or RBV and IFN). Nor do they teach or fairly suggest administering EPO prior to the onset of RBV-induced anemia in HCV patients, i.e., including EPO in HCV treatment.

Accordingly, it is firmly believed that the herewith cited documents should not negatively impact upon the previous indication of the allowability of the now pending claims; and, that a Notice of Allowance may promptly issue.

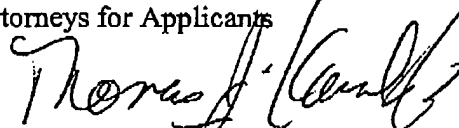
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The filing of this Information Disclosure Statement is not an admission that the documents identified herein constitute prior art to the present application.

As this report is being filed with a Request for Continued Examination and an Amendment, it is believed no fee is required. However, the Examiner is authorized to charge any additional fees, or credit any overpayments, to Deposit Account No. 50-0320.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP  
Attorneys for Applicants



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Encs. PTO Form 1449  
References (2)

Sheet 1 of 1

Based on Form PTO-1449 (3/90)	ATTY. DOCKET NO.	SERIAL NO.
	144001-2001	09/862,404
	LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)	
APPLICANT		
Douglas T. Dieterich		
FILING DATE	GROUP	
May 21, 2001	1647	

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AL							
	AM							
	AN							
	AO							
	AP							

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AQ		Weisz KB, JF Braun, DT Dieterich, PF Hergenroeder, SJ Kreiswirth, MP Mullen, AA McMeeking, R Tirelli, "Erythropoietin use for ribavirin/interferon-induced anemia in Hepatitis C patients," [abstract], Proceedings of the 38 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC): September 24-27, San Diego, California, 1998.
AR		Weisz K, T Hau, S Kreiswirth, M McMeeking, J Braun, J Tirelli, AH Talal, DT Dieterich, "Erythropoietin use for ribavirin/interferon induced anemia in patients with Hepatitis C," [poster], Proceedings of the 38 <sup>th</sup> Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC): September 24-27, San Diego, California, 1998.
AS		
AT		
AU		
AV		

EXAMINER	DATE CONSIDERED
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\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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